JUN - 6 2001

510 (k) Summary

HEMOCHRON® Kaolin –Activated Heparin and Protamine Dosing Assays

This summary of safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K010193

Prepared: January 18, 2001

Submitted by: John Clay
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Device Name

Common / Usual Name: Heparin and Protamine Response Tests
Product Name: HEMOCHRON® Kaolin –Activated Heparin and Protamine Dosing Assays

Predicate Device

HEMOCHRON® Protamine Dosing Assay (K870831)
HEMOCHRON® Heparin Response Test (K904003/A)
HEMOCHRON® Protamine Response Test (K910105)

Device Description and Technological Characteristics

The HEMOCHRON® kaolin-activated dosing assays are a modification to the diatomaceous earth (DE) activated dosing assays, which have previously been cleared for market. The Hemochron dosing assays are in the form of glass test tubes containing a blood coagulation activator (kaolin) and lyophilized quantities of heparin or protamine depending on the test type. The Kaolin-HRT contains heparin and the Kaolin-PRT, Kaolin-PDAO both contain protamine. The predicate devices use diatomaceous earth (DE) as the blood coagulation activator, while the assays, which are the subject of this application are activated by kaolin.
Kaolin-activated assays have been developed as an alternative to the diatomaceous earth activated tests. Diatomaceous earth activated test results are artificially prolonged in the

presence of aprotinin (Tradename -Trasylol, Bayer Pharmaceuticals), a drug frequently administered during cardiac surgery to decrease blood loss. However, kaolin based assays, are not affected by aprotinin in the same manner. While both DE and kaolin based activated clotting time tests (ACT) are available for the Hemochron system, only the DE based dosing assays are currently available. This 510k submission provides kaolin based dosing assays for clinical use in cases employing aprotinin.

Statement of Intended Use

The HEMOCHRON® Kaolin Based Dosing Assays are intended for professionals to monitor and manage the heparin and protamine doses administered to patients during interventional cardiology and cardiac surgery.

For In Vitro Diagnostic Use Only

Summary of Performance Data

COMPARATIVE DATA

HRT and PRT Tests

Laboratory and clinical data were obtained comparing performance characteristics of the K-HRT with the HRT, and the K-PRT with the PRT. Additional studies were performed to determine the aprotinin sensitivity of these assays.

In laboratory assays, samples from normal donors, not taking medications, were analyzed using the kaolin-based tests. Heparin, at a final concentration of 3.0 units/ml, was added to samples to be analyzed using the kaolin based assays. Aprotinin was also added, in increasing concentrations, to the samples to be analyzed. The aprotinin concentrations used were selected to exceed the stated steady state concentrations in patients receiving a full Hammersmith dose of aprotinin (270 KIU/ml). Results of testing demonstrate that there is no clinically or statistically significant difference in the calculated doses obtained in samples containing up to 500 KIU/ml aprotinin compared to those without aprotinin. **(P>0.20)**.

Clinical comparisons employed the diatomaceous earth (DE) and kaolin activated dosing assays in parallel on samples from patients undergoing elective cardiac surgery. There was a high degree of correlation between both clotting times and predicted doses for the DE and kaolin systems.

Clotting Time Comparison	**Predicted Dose Comparison**	
HRT - (R = 0.83)	**Heparin Dose -**	**(R = 0.88)**
PRT- (R = 0.85)	**Protamine Dose -**	**(R = 0.85)**

PDAO Tests

Laboratory comparisons of the predicate PDAO assay with the kaolin PDAO assay were performed. Heparin, in varying levels, was added to each sample prior to testing on both kaolin and diatomaceous earth activated PDAO assays. The decrease in clotting time with decreasing heparin concentration for each test was compared.

Both DE and kaolin activated assays performed within specifications. A direct comparison of the two systems showed an excellent correlation with a slope approaching 1.0 and a correlation coefficient of **(R= 0.958)**.

Conclusion:

The technological characteristics and intended use of the Kaolin-Activated Dosing Assays are substantially equivalent to the Predicate Diatomaceous Earth-Activated Dosing Assays. The Kaolin-Activated Dosing Assays provide the clinician with alternative assays for the dosing of heparin and protamine in the presence of aprotinin.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN - 6 2001

Mr. John Clay
Regulatory Affairs Manager
International Technidyne Corporation
8 Olsen Avenue
Edison, New Jersey 08820

Re: K010193
Trade Name: HEMOCHRON® Kaolin – Activated Heparin and Protamine Dosing Assays
Regulation Number: 21 CFR § 864.7525
Regulatory Class: II
Product Code: KFF
Dated: April 19, 2001
Received: April 20, 2001

Dear Mr. Clay:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (If Known): K010193

Device name: HEMOCHRON® Kaolin Activated Dosing Assays

Indications for Use:

The HEMOCHRON® Kaolin Based Dosing Assays are intended for professionals to monitor and manage the heparin and protamine doses administered to patients during interventional cardiology and cardiac surgery.

For In Vitro Diagnostic Use Only

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K010193

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over- the- Counter Use_____
Per 21 CFR 801.109

(Optional Format 1-2-96)